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09/808,275	03/14/2001	Randall W. Nelson	530-013	4255

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EXAMINER

COUNTS, GARY W

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/808,275

Applicant(s)

NELSON ET AL.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 6 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 31-44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### **Status of the claims**

The preliminary amendment filed May 24, 2002 has been considered and entered. Claims 1-30 have been cancelled.

### ***Specification***

The attempt to incorporate subject matter into this application by reference to the Nelson et al article on page 6 is improper because material essential to the practice of the invention can be incorporated by reference only if the reference is a US patent or an allowed US application in which the issue fee has been paid. See *In re Fouche* 169 USPQ 429; 439 F.2d 1237 (CCPA 1971).

The use of the trademark Lumonics HY 400 has been noted in this application on page 41. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

The disclosure is objected to because of the following informalities:

On page 4, line 19 of the specification between the disclosure "field bimolecular" insert --of--.

On page 5, line 26 "quantification" should be --quantitative--.

On page 6, lines 22-23 it is recommended to delete [and is herein incorporated by reference].

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On page 17, line 12 it is recommended to insert --,-- after the term nylon.

On page 36 at the end of the second paragraph it is recommended to insert --,--.

On page 46 at the end of the last paragraph it is recommended to insert --,--.

Appropriate correction is required.

### ***Claim Objections***

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 48-61 have been renumbered 31-44 respectively.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 33, 35, 38, 40, 42 and 44 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In claims 33, 35, 38, 40, 42 and 44 a recitation of "there is a filter element to which the affinity reagent is bound", but there is no support for this limitation disclosed

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anywhere in the specification. On pages 40-41 applicant disclose beads having affinity reagent immobilized thereon and Applicant discloses slurried affinity reagent incubated with specimen and internal reference. Applicant also disclosed the affinity reagent contains myotoxin  $\alpha$  affinity bound to the retain anti-myotoxin  $\alpha$ , which was physically separated from the specimen by forcing the volume through the backside of a P-10, 10 $\mu$ L filter pipette tip thereby retaining the affinity reagent on the filter. The applicant does not disclose a filter element to which the affinity reagent is bound. There is no description in the specification disclosing that the affinity reagent is bound to a filter element.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 31, line 1 the recitation "certain" is vague and indefinite. There is no definition provided in the specification for the term and it is unclear what the term is referring to. See deficiencies throughout the claims.

Claim 31 the recitation "involving the use of an affinity reagent" and "through the use of a mass spectrometer" is vague and indefinite. It is unclear what is meant by "involving the use" and "through the use". Are the affinity reagent and the mass spectrometer actually used in the process? See also deficiencies found in claim 34.

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Claim 31, part (c) the recitation "via" is vague and indefinite. It is unclear what the term encompasses.

Claim 32 is vague and indefinite because of the lettering of the method steps are not in sequential order. It is unclear if step (a) in claim 32 is trying to replace step (a) of claim 31 or if it is an additional step. See also deficiencies for steps (b) and (c).

Claim 32, part (b) "an unbound remainder" is vague and indefinite. It is unclear if unbound remainder is referring to unbound affinity reagent or unbound analyte or something else. See also deficiencies found in claim 37 and 41, part (b).

Claim 32, part (e) "the unique mass-to-charge ratio" there is insufficient antecedent basis for this limitation. See also deficiencies found in claim 37 and 41, part (e).

Claim 33, 35, 38, 40, 42 and 44 are vague and indefinite. It is unclear if the affinity reagent is bound to the filter prior to the binding to the analyte or if the affinity reagent is bound to the filter after binding to the analyte. Furthermore, there is no support in the specification for an affinity reagent bound to the filter.

Claim 36, line 1, the recitation "any of one or more certain analyte species" is vague and indefinite. It is unclear whether determination is for specific analyte species or all analyte species are being claimed.

Claim 37 is vague and indefinite because of the lettering of the method steps are not in sequential order. It is unclear if step (a) in claim 37 is trying to replace step (a) of claim 36 or if it is an addition step. See also deficiencies found for steps (b) and (c).

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Claim 41 is vague and indefinite because of the lettering of the method steps are not in sequential order. It is unclear if step (a) in claim 41 is trying to replace step (a) of claim 36 or if it is an addition step. See also deficiencies found for steps (b) and (c).

Claim 41, line 2 "plurality" is vague and indefinite. It is unclear if there is many of the same antibody immobilized to the solid substrate or if there is many different antibodies immobilized to the solid substrate.

### ***Double Patenting***

1. Claims 31, 36 and 41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 09/808314. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to determine and identify the analyte by using mass spectrometry for molecular weight analysis.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

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(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

3. Claims 31, 32, 36, 37, and 41 are rejected under 35 U.S.C. 102(a) as being anticipated by Nelson et al (Mass Spectrometric Immunoassay, Analytical Chemistry 1995, 67, 1153-1158).

Nelson et al disclose a method to determine an analyte by capturing and isolating an antigen. Nelson et al disclose incubating antibodies covalently immobilized to a solid support with an antigen-containing sample. Nelson et al disclose that after incubation and the formation of antibody/antigen complexes (post-combination affinity reagent), the complexes are washed and then the antigen is eluted onto a mass spectrometer probe tip using a solution of MALDI matrix. Nelson et al. further disclose that after the antigen is eluted that Time-of-flight mass spectrometry is performed (page 1153 col 2, see also Experimental Section). Nelson et al also disclose that a single assay can be used to screen biological systems for the presence of multiple, mass-resolved antigens. Nelson et al also disclose that antigen signals are observed at characteristic mass-to-charge values in the mass spectrum. Nelson et al also disclose a plurality of antibodies on a solid substrate (Experimental Section). Nelson et al also disclose that the affinity reagent-antigen complex is retained in a filter pipette tip (Figure 1 and description of Figure 1).

4. Claims 31 and 36 are rejected under 35 U.S.C. 102(e) as being anticipated by Koster et al (US Patent 5,605,798).



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Koster et al disclose a mass spectrometric method for determining if a particular analyte (nucleic acid sequence) is in a biological sample. Koster et al disclose capturing and isolating the analyte by using an affinity reagent (capture nucleic acid molecule), which has been immobilized to a solid support (col 3, lines 50-67). Koster et al also disclose that the method allows for the analyte to be detected and identified by its specific molecular weights.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 34, 39 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al in view of Papac et al (Direct analysis of Affinity-Bound analytes by MALDI/TOF MS, Analytical Chemistry 194, 66, 2609-2613).

See above for teachings of Nelson et al.

Nelson et al differ from the instant invention in failing to disclose adding a disassociation agent to the isolated post-combination affinity reagent prior to the step of adding the laser desorption/ionization agent.

Papac et al disclose sample preparation can influence the spectra observed and that for immobilized affinity chromatography, a 3 times stronger signal is observed when the supernatant is used for analysis ( a dissociation reagent is used before application of the desorption/ionization agent) compared with mixing the MALDI matrix with the

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beads on the target (p. 2613, 3<sup>rd</sup> paragraph) and that immobilized affinity chromatography differs from conventional chromatography in that it exploits specific biological interactions such as those of an antibody and antigen which demonstrate high specificity associated affinity binding and that, either half of a biological interaction can be used in the stationary phase as an immobilized ligand (p. 2609, paragraph 1).

It would have been obvious to one of ordinary skill in the art to incorporate the use of a dissociation reagent as taught by Papac et al into the method of Nelson et al because Papac et al show that this dissociation reagent allows for a 3 times stronger signal.

7. Claims 33, 38, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al in view of Raybuck et al (US Patent 5,833,927).

See above for teachings of Nelson et al.

Nelson et al differ from the instant invention in failing to disclose a filter element to which the affinity reagent is bound.

Raybuck et al disclose a micropipette tip comprising a porous membrane which can act as a filter and also has antibodies bound to the surface for capturing the corresponding analyte (col 5, lines 30-59). Raybuck et al disclose that this membrane provides for a device for capturing a component present in a fluid and provides the advantage of capturing the desired component on or at or in the forward-facing surface of the membrane thus allowing for easy access for subsequent treatment (col 6, lines 26-32).

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It would have been obvious to one of ordinary skill in the art to incorporate the substitute the membrane (filter) of Raybuck et al for the filter of Nelson et al because Raybuck et al shows that this membrane provides for a device for capturing a component present in a fluid and provides the advantage of capturing the desired component on or at or in the forward-facing surface of the membrane thus allowing for easy access for subsequent treatment.

8. Claims 35, 40 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al in view of Papac et al as applied to claims 31, 32, 34, 36, 37, 39, 41 and 43 above, and further in view of Raybuck et al.

See above for teachings of Nelson et al and Papac et al.

Nelson et al and Papac et al differ from the instant invention in failing to disclose a filter element to which the affinity reagent is bound.

Raybuck et al disclose a micropipette tip comprising a porous membrane which can act as a filter and also has antibodies bound to the surface for capturing the corresponding analyte (col 5, lines 30-59). Raybuck et al disclose that this membrane provides for a device for capturing a component present in a fluid and provides the advantage of capturing the desired component on or at or in the forward-facing surface of the membrane thus allowing for easy access for subsequent treatment (col 6, lines 26-32).

It would have been obvious to one of ordinary skill in the art to incorporate the substitute the membrane (filter) of Raybuck et al for the filter of Nelson et al because Raybuck et al shows that this membrane provides for a device for capturing a

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component present in a fluid and provides the advantage of capturing the desired component on or at or in the forward-facing surface of the membrane thus allowing for easy access for subsequent treatment.

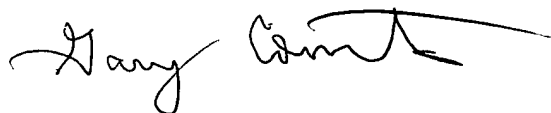
**Conclusion**

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gary W. Counts  
Examiner  
Art Unit 1641  
July 15, 2002



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07/15/02